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PORTER WRIGHT MORRIS & ARTHUR, LLP
INTELLECTUAL PROPERTY GROUP
41 SOUTH HIGH STREET
28TH FLOOR
COLUMBUS, OH 43215

EXAMINER	
TOSCANO, ALICIA	
ART UNIT	PAPER NUMBER
1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,449	YAMANE ET AL.	
	Examiner	Art Unit	
	ALICIA M. TOSCANO	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,26,28 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,26,28 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/16/10 has been entered.

Declaration under 1.132

2. As previously set forth in the action dated 11/19/09: Applicant's declaration is not persuasive. Applicant has shown that one expects a linear relationship between viscosity and molecular weight, a facet the Examiner generally agrees with. The Examiner does not, however, agree that the same linear relationship would exist between the same polymer MW/concentrations and different solvent/temperature systems. Given Applicant's data set measuring the viscosity in dimethyl sulfoxide and hexafluoroisopropanol at 25C, Applicant argues that the 0.09 change in viscosity of PGA measured in trichlorophenol/phenol at 30C in Matsumoto relates to only a 14,000 MW increase in Matsumoto. Applicant thusly argues that this small change does not meet the chain lengthening of the claims.

The Examiner disagrees. One cannot take the viscosity at a one temperature and solvent and super-impose it onto a data set at a second temperature and solvent

and drawn any conclusions therein on the resulting MW. As such Applicant's data is not persuasive. Further, even if said data were commensurate, a 14,000 MW increase must be due to some chain lengthening since (1) the 14,000 MW is an average therein and (2) Matsumoto meets Applicant's claimed method. Applicant's claims only require 1 such polymer to be chain lengthened, and as such it would be the Examiner's position that 1 polymer chain therein must be chain lengthened to an extent to meet that of Applicant's claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 11, 26 and 28, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto.

Elements of this rejection are as set forth in the action dated 11/19/09 reiterated below in its entirety. Regarding newly amended claims 11 and 26: the ranges at least 1.35, not higher than 300C, 5 to 40, 120,000 to 500,000, at least 1.90, at least 3C and at least 233C are broader than the previous ranges and thusly met by elements already set forth, regarding the new range "3 to 10 parts by weight" of the chain-lengthening reactant, Matsumoto discloses the desire to have a content of unreacted terminal blocking agent of 5 wt% or less in the molded article [0021]. In order to have 5 wt% remaining after reaction, the composition would have to include at least that much during reaction. Since the main component (or at least 50%) of the composition of

Matsumoto would have to be the polyesters, the Examiner finds this to implicitly disclose a range of blocking agent up to about 50 wt%. As such a prima facie case of obviousness exists over the claimed range. See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. Claims 32-37 have been added, elements therein are as addressed previously and below. See remarks below.

Matsumoto discloses aliphatic polyesters. Said polyesters are the reaction product of polylactic acid and an oxazoline (abstract). The polylactic acid may be produced from the ring opening polymerization of a cyclic dimer [0010]. Polyglycolic acid may be used [0009]. The oxazoline compound may be 2,2'-diphenylene bis(2-oxazoline) [0014], [0021] and examples. The oxazoline is reacted at a temperature of around 220C [0036]. The molecular weight of the polylactic acid, before reaction with oxazoline, is from 50,000 to 300,000 [0010]. When polyglycolic acid is used it is the Examiner's position that one would use the same MW as taught for use for the polylactic acid, since Matsumoto teaches the polymers as functional equivalents. Matsumoto discloses the use of the oxazoline to terminate the carboxyl end groups of the polylactic acid, however, it is the Examiners position that use of the bis(2-oxazoline) inherently crosslinks, or chain extends, via reaction between two neighboring polylactic acid end groups since this is the same reaction composition and method used by Applicant. Since the oxazoline will inherently bond two ends of neighboring polylactic

acid chains the Examiner finds the increase in molecular weight to be inherent in the reaction of Matsumoto.

It is the Examiners position that a MW ratio, the property requirements of T2-T1, a PDI of 1.9 and an end MW of 150,000 would be inherent in the composition. If there is any difference between the above composition and the composition of the instant claims the difference would have been minor and obvious. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773, 22 USPQ 313 (EDNY 1934).

Matsumoto does not disclose a reaction time of between 10 and 30 minutes, as required by Claim 11. As set forth in the arguments dated 6/2/09, generally, the higher the reaction temperature the shorter the reaction time, however it is unclear to the Examiner what a reasonable reaction time would be. The reaction would not be instantaneous and residence times within the 10-30 minutes claimed by Applicant's would not be unrealistic. As such a prima facie case of obviousness exists for the claimed range.

Since the composition elements and processing conditions are met as previously set forth the properties, chain lengthening, end MW, PDI and (T2-T1) difference therein are found inherent.

Regarding the temperature limitation of not lower than the melting temperature but no higher than 240C: Matsumoto exemplifies the use of PLA (polylactic acid) and PGA (polyglycolic acid). Matsumoto discloses a reaction temperature of 220C when using PLA and 270C when using PGA. The melting point of PGA is 224C and the melting point of PLA is 176C. As such Matsumoto is using a reaction temperature, in both instances, of about 45 degrees higher than the melting point, which does not anticipate the claimed temperature range. However, since the polymers are in the melted state it is the Examiner's position that the degree of heating above melting point does not affect the polymers reactivity (i.e. one could pick any temperature within reason above the melting temperature but below that which the polymer would degrade or burn), and the chosen temperature above the melting point is a result effective variable, increasing the temperature decreases the melt viscosity, and vice versa. Further, the reaction between the oxazoline and polymer would also be affected by the temperature, wherein a faster reaction time would be expected as one increases the temperature, and vice versa.

As such the Examiner finds that a prima facie case of obviousness exists to optimize the temperature depending on the viscosity and reaction time desired, meeting the temperature requirements of the claims.

Remarks:

Applicant argues Matsumoto indicates that the polymerization does not progress by adding the oxazoline compound and Matsumoto does not teach or suggest further enhancing the polymerization degree of the polymer by chain lengthening and as such does not disclose the method of the claims. Applicant argues the 3 to 10 wt% is not met. Applicant argues a comparison of the claimed process is difficult to provide in view of the failure of Matsumoto to disclose important details of his process. Applicant argues the only PGA reaction temperature Applicant can find is 270C, not meeting the "not higher than 240C" requirements of the claims. Applicant argues that though their process and Matsumoto are strikingly similar there are limitations required in the claims that are not disclosed in Matsumoto and these teachings would not have been obvious to one of ordinary skill in the art. Applicant argues Matsumoto does not disclose the MW before or after end capping. Applicant argues there is no teaching in Matsumoto as to the functional equivalence between polylactic acid and polyglycolic acid. Applicant argues significant differences in solution viscosities would indicate that PLA and PGA are not functional equivalents. Applicant argues only a slight difference in viscosity is found in the examples of Matsumoto, indicating only a small change in MW. Applicant argues Matsumoto does not necessarily teach that a 1.35 MW increase will result from the reaction.

The Examiner disagrees. The Examiner finds no evidence to support Applicant's arguments that adding oxazoline does not enhance the polymerization of the polymer. The Examiner agrees that Matsumoto first polymerizes the starting polymers prior to addition of the oxazoline, however this facet is moot because the oxazoline reaction is

so strikingly similar to that of Applicant and as such all the MW increases and properties thereof have been deemed inherent. That Matsumoto does not recognize that some portion (even a small one thereof) increases in chain length is moot, since this must inherently happen in the reaction of Matsumoto given the similarities in composition and method. Arguments therein are thusly moot. The new wt% of the claims has been addressed above and is met by Matsumoto, as such arguments therein are found moot. Though it may be hard to exactly recreate Matsumoto due to the lack of some small details, the Examiner submits that a close approximation thereof can be performed. Such an experiment, which would include both PLA and PGA in order to support various arguments made by Applicant, if it showed an unexpected result, would be sufficient to overcome the current rejections. Without a close approximation of showings commensurate with Matsumoto Applicant's arguments continue to be moot given the similarities in the compositions and methods. Arguments therein are thusly moot. A position of using any temperature above the melting temperature of PGA has been put forth, thusly the lack of teachings in Matsumoto over this facet are found moot. The Examiner has put forth obvious rejections over the various facets in Applicant's claims which are not explicitly stated in Matsumoto. Applicant may choose to rebut these positions with showings of unexpected results, however without such the arguments above related to such are not found persuasive. That Matsumoto does not disclose the MW before and after capping is moot since one reasonably expects the same product as Applicant. Matsumoto teaches PLA and PGA to function equivalently as polyesters for reaction with oxazoline. He teaches that either one may be chosen for said reaction.

Thusly he teaches them to function equivalently therein. That they have different viscosities is not an indicator that they are not functional equivalents since one would expect different polymers to have different properties. Applicant may show unexpected results stemming from the use of PGA, however without such arguments therein will continue to not be persuasive. Solution viscosities cannot be used in the analysis of MW for reasons already set forth. Arguments therein are found moot. The Examiner requests evidence that a 1.35 MW increase would not necessarily stem from the reaction of Matsumoto. It is unclear why when Applicant and Matsumoto have such strikingly similar reactions and compositions the 1.35 MW would not be an inherent feature. Without evidence to the contrary Applicant's arguments are not persuasive and the rejections stand as set forth above.

4. Claims 11, 26 and 28, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore in view of Matsumoto.

Elements of this rejection is as set forth in the action dated 6/2/08 reiterated below in its entirety. Regarding newly amended claims 11 and 26: the ranges at least 1.35, not higher than 300C, 5 to 40, 120,000 to 500,000, at least 1.90, at least 3C and at least 233C are broader than the previous ranges and thusly met by elements already set forth, regarding the new range "3 to 10 parts by weight" of the chain-lengthening reactant, Matsumoto discloses the desire to have a content of unreacted terminal blocking agent of 5 wt% or less in the molded article [0021]. In order to have 5 wt% remaining after reaction, the composition would have to include at least that much

during reaction. Since the main component (or at least 50%) of the composition of Matsumoto would have to be the polyesters, the Examiner finds this to implicitly disclose a range of blocking agent up to about 50 wt%. As such a prima facie case of obviousness exists over the claimed range. See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. Claims 32-37 have been added, elements therein are as addressed previously and below. See remarks below.

Bonsignore discloses the production of high molecular weight polylactic acid or polyglycolic acid. Bonsignore discloses that since relatively small amounts of polylactic acid are used in industry it is very expensive to obtain large MW polylactic acid with high purity and discloses reacting the carboxyl end groups of the polylactic acid with bis-oxazoline (abstract) is a way to obtain the desired purity and MW less expensively (Column 2 lines 14-19). The polylactic acid or polyglycolic acid may be produced by the ring opening polymerization of dilactones (Column 3 Lines 62-65). The molecular weight of the polylactic acid before the reaction is 2,000-15,000 (Column 1 Line 17). The molecular weight after reaction with a bis-oxazoline is 50,000-100,000 (Column 6 Lines 26-28).

Bonsignore does not disclose the use of an end MW of greater than 181K or the use of at least 30,000 MW PGA as a starting material as required by Claim 11.

Matsumoto includes elements as set forth above. Matsumoto discloses the use of a polylactic acid of MW between 100k and 300k because when the MW is within this range the physical properties, such as strength, are excelled [0010].

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of a MW of 50,000 to 400,000, as taught by Matsumoto, in order to create articles with superior physical properties.

The start range of at least 30,000 and the end range of at least 150,000 lies within this range.

The polydispersity of polymer compositions is high unless specific conditions are met to yield a low PDI. Since the reaction conditions of the polylactic acid has been met the Examiner finds the PDI of at least 1.9 to be inherent in the composition of Bonsignore. As the composition requirements have been met the Examiner finds the properties of the claims to be inherent.

If there is any difference between the above composition and the composition of the instant claims the difference would have been minor and obvious. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP 2112.01(I) , *In re Best*, 562 F2d at 1255, 195 USPQ at 433, *Titanium Metals Corp v Banner*, 778 F2d 775, 227 USPQ 773 (Fed Cir 1985), *In re Ludtke*, 441 F2d 660, 169 USPQ 563 (CCPA 1971) and *Northam Warren Corp v D F Newfield Co*, 7 F Supp 773, 22 USPQ 313 (EDNY 1934).

Bonsignore does not include the use of a specific bis-oxazoline nor the amount of bis-oxazoline useful to create high molecular weight polylactic acid.

Matsumoto discloses the use of 0.5-2 wt% 2,2'-m-phenylene bis(2-oxazoline) [0021], Examples, Table 1. 2,2'-m-phenylene bis(2-oxazoline) is preferred because of its stability with the polyester resin [0021], and the amount used is preferred so as to minimize the amount of unreacted bis-oxazline in the composition [0021]. The amount should be minimized so as to have less than 5 wt% of unreacted oxazoline in the end product in order to obtain good end molding properties [0021]. Since the polyester is the main component therein, this would implicitly imply a range of small amounts up to about 50 wt%.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Bonsignore the use of up to 50 wt% of 2,2'-m-phenylene bis(2-oxazoline), as taught by Matsumoto, since this amount of said species is taught to have superior stability in the resin and this would thusly lead to a superior end product, further meeting the requirements of claims 11 and 28.

Bonsignore does not disclose the reaction time. The time of reaction will dictate the crosslink density and thus the molecular weight of the polylactic-co-oxazoline product. The molecular weight of the polylactic acid dictates the overall properties of the resin. Higher molecular weight will yield better strength and mechanical properties than low molecular weight polymer however too high of a molecular weight will lead to difficulties with molding.

It would have been obvious to one of ordinary skill in the art at the time of the invention to tailor the reaction time of Bonsignore in order to achieve the desired crosslink density, or molecular weight, of the polylactic acid in order to create articles with superior molding properties.

Additionally, as set forth in the arguments dated 6/2/09, generally, the higher the reaction temperature the shorter the reaction time, however it is unclear to the Examiner what a reasonable reaction time would be. The reaction would not be instantaneous and residence times within the 10-30 minutes claimed by Applicant's would not be unrealistic. As such a prima facie case of obviousness exists for the claimed range.

As the compositional requirements are met the Examiner finds the MW increase and further properties such as PDI, T2-T1 difference and weight loss starting temperature required by the Claims to be inherent.

Regarding the temperature limitation of not lower than the melting temperature but no higher than 240C of claim 11 and its dependants: Bonsignore discloses that either polylactic acid or polyglycolic acid may be used. Bonsignore recognizes that PLA has a melting point of about 175 whereas PGA has a melting point of about 230 (Column 4 lines 26-34). Bonsignore discloses solution polymerization in the Examples, Bonsignore does not disclose melt polymerization.

Matsumoto includes elements as set forth above. Matsumoto discloses melt polymerization as a suitable reaction process for the same reaction taught in Bonsignore.

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945), a prima facie case of obviousness exists to use the process of Matsumoto to react the polymers of Bonsignore, since the process is taught to be suitable for such. Since the polymers in Matsumoto are in the melted state it is the Examiner's position that the degree of heating above melting point does not affect the polymers reactivity (i.e. one could pick any temperature within reason above the melting temperature but below that which the polymer would degrade or burn), and the chosen temperature above the melting point is a result effective variable, increasing the temperature decreases the melt viscosity, and vice versa. Further, the reaction would also be affected by the temperature, wherein a faster reaction time would be expected as one increases the temperature, and vice versa.

As such the Examiner finds that a prima facie case of obviousness exists to optimize the temperature depending on the viscosity and reaction time desired, meeting the temperature requirements of the claims.

Remarks:

Applicant argues Bonsignore provides no basis for one of ordinary skill to apply any of Bonsignore's teachings to glycolic acid. Applicant argues Applicant's starting MW is within the desired end MW of Bonsignore. Applicant argues the reaction parameters of the claims are not met and the reactions of Bonsignore are significantly different than Applicant's. Applicant argues Bonsignore discloses using reaction

temperatures below the melting point. Applicant argues the Examiner's statements regarding the melting point and Matsumoto are unsupported and conflicting. Applicant argues Matsumoto teaches endcapping and there is no reason to combine the two references. Applicant argues Matsumoto does not disclose the wt% of the claims.

The Examiner disagrees. Bonsignore discloses that either lactic acid or glycolic acid may be used. As such it is proper to apply the teachings of Bonsignore to glycolic acid and arguments therein are moot. That the starting MW is within the end desired range of Bonsignore is moot since Matsumoto has been used to overcome this deficiency. Bonsignore discloses the claimed reaction but exemplifies different reactions therein. Any arguments drawn to these different reactions are not found persuasive. Matsumoto is a suitable combination given the similarities in the reactants of the compositions. As such one looking for reaction conditions in Bonsignore for oxazoline would have a reasonable expectation of success when using the teachings of Matsumoto. The operating parameters have been deemed prima facie obvious and since some degree (even if only a small portion) of chain lengthening must be inherent in Matsumoto, Applicant's arguments are not found persuasive. The Examiner does not find the temperature statements to be conflicting, once a polymer is melted it does not matter what temperature above the melting temperature is used, as long as you do not degrade the polymer. The temperature is also generally recognized as a reaction parameter in that increasing the temperature will increase reaction rates (in this case it will affect the reaction between the oxazoline and polyester). The wt% of the claims is

met, as set forth above. The positions set forth are found proper. Applicant's arguments are not found persuasive and stand as set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is (571)272-2451. The examiner can normally be reached on M-F 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia M Toscano/

Examiner, Art Unit 1796